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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,258	05/24/2006	Isabel Ottinger	33568-US-PCT	3217

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,258	OTTINGER, ISABEL	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending.

Claims 27-28 have been canceled.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-4, 6-8 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Silver et al (PG-Pub 2005/0209141 A1 effective filing date October 17, 2003).

Silver et al disclose the instantly claimed invention directed to a composition that comprises Aliskiren (see [0070], rennin inhibitors), which is a gamma-amino-delta-hydroxy-omega-aryl-alkanoic acid amide rennin inhibitor, formulated into a microemulsion (see Silver

paragraph [0150]), wherein the microemulsion comprises *one or more organic* solvent(s) that is/are acceptable from the physiological standpoint, chosen, in addition to water, from solvents such as acetone, ethanol, isopropyl alcohol, glycol ethers such as the products sold under the name "*Dowanol,*" *polyglycols and polyethylene glycols, C.sub.1-C.sub.4 alkyl esters of short-chain acids, ethyl or isopropyl lactate, fatty acid triglycerides* such as the products marketed under the name "Miglyol," isopropyl myristate, animal, mineral and vegetable oils and polysiloxanes together with an adjuvant chosen from antioxidants, surfactants, other preservatives, film-forming, keratolytic or comedolytic agents, perfumes, flavorings and colorings.

Silver also discloses a method that comprises the step of administering Aliskiren to a patient (see claim 24)

Silver et al claims: A method for treating or preventing a condition in which renin is overly active in a patient comprising administering to the patient a composition that can inhibit renin release from a mast cell.

2. The method of claim 1, wherein the condition is associated with increased numbers of mast cells.

3. The method of claim 1, wherein the condition wherein the condition leads to increased angiotensin formation.

4. The method of claim 1, wherein the condition wherein the condition is associated with an inflammation.

5. The method of claim 1, wherein the condition is myocardial ischemia.

6. The method of claim 1, wherein the condition is congestive heart failure, atherosclerotic coronary artery disease, or chronic obstructive pulmonary disease.

7. The method of claim 1, wherein the condition is chronic obstructive pulmonary disease, Cor pulmonale, bronchiectasis, acute respiratory distress syndrome, bronchiolitis obliterans-organizing pneumonia, cystic fibrosis, interstitial lung diseases, silicosis, sarcoidosis, lung cancer, tuberculosis, gastritis, peptic ulcer, hepatocellular carcinoma, ulcerative colitis, Crohn's disease, liver cirrhosis, hepatitis, pancreatitis, atherosclerosis, myocardial infarction, congenital

heart disease, myocarditis, cardiomyopathy, brain infarction, diabetes, thyroiditis, osteoporosis, glomerulonephritis, nephropathy, multiple sclerosis, rheumatoid arthritis, osteoarthritis, rheumatic arthritis congestive heart failure, cardiac hypertrophy, hypertension, cardiomyopathy, asthma, endometriosis, brain infarction, liver fibrosis, lung fibrosis, kidney fibrosis, heart fibrosis, skin fibrosis, interstitial cystitis, pancreatic cancer, or cardiomyopathy.

8. The method of claim 1, wherein the composition that can inhibit renin release from a mast cell comprises lodoxamide, cromolyn sodium, nedocromil, nicardipine, barnidipine, YC-114, elgodipine, niguldipine and R(-)-niguldipine, a dihydropyridine, nicardipine or nifedipine.

9. The method of claim 1, wherein the composition further comprises an ACE inhibitor.

10. The method of claim 9, wherein the ACE inhibitor is enalaprilat.

11. The method of claim 1, wherein the composition further comprises an angiotensin type 1 receptor inhibitor.

12. The method of claim 11, wherein the angiotensin type 1 receptor inhibitor is valsartan, olmesartan, candesartan, irbesartan, losartan or telmisartan.

13. The method of claim 1, wherein the composition further comprises an agent that can inhibit sodium/hydrogen exchange type-1 (NHE-1) transport systems.

14. The method of claim 1, wherein the composition is administered locally into cardiac, vascular, lung, liver, cervical, intestinal, muscle, pancreatic, brain, kidney or skin tissues.

15. The method of claim 1, wherein the composition is administered locally via a sustained release implant.

16. The method of claim 1, wherein the composition is administered locally via a stent.

17. A method for treating or preventing a condition in which renin is overly active in a patient comprising locally administering to an affected organ in the patient a composition that can inhibit renin expression or activity.

18. The method of claim 17, wherein the condition is associated with increased numbers of mast cells.

19. The method of claim 17, wherein the condition wherein the condition leads to increased angiotensin formation.

20. The method of claim 17, wherein the condition wherein the condition is associated with an inflammation.

21. The method of claim 17, wherein the condition is myocardial ischemia.

22. The method of claim 17, wherein the condition is congestive heart failure, atherosclerotic coronary artery disease, or chronic obstructive pulmonary disease.

23. The method of claim 17, wherein the condition is chronic obstructive pulmonary disease, Cor pulmonale, bronchiectasis, acute respiratory distress syndrome, bronchiolitis obliterans-organizing pneumonia, cystic fibrosis, interstitial lung diseases, silicosis, sarcoidosis, lung cancer, tuberculosis, gastritis, peptic ulcer, hepatocellular carcinoma, ulcerative colitis, Crohn's disease, liver cirrhosis, hepatitis, pancreatitis, atherosclerosis, myocardial infarction, congenital heart disease, myocarditis, cardiomyopathy, brain infarction, diabetes, thyroiditis, osteoporosis, glomerulonephritis, nephropathy, multiple sclerosis, rheumatoid arthritis, osteoarthritis, rheumatic arthritis congestive heart failure, cardiac hypertrophy, hypertension, cardiomyopathy, asthma, endometriosis, brain infarction, liver fibrosis, lung fibrosis, kidney fibrosis, heart fibrosis, skin fibrosis, interstitial cystitis, pancreatic cancer, or cardiomyopathy.

24. The method of claim 17, wherein the composition that can inhibit renin activity comprises BILA2157, **aliskiren**, remikiren, ankiren or enalkiren.

Silver et al anticipate the instantly claimed invention as now claimed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 5, 9-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silver et al as applied to claims 14, 6-8 and 26 above in view of Owen et al (US Pat. 5,633,226).

See discussion of Silver et al above. Silver et al describe and show compositions of microemulsions that comprise aliskiren, a gamma-amino-delta-hydroxy-omega-aryl-alkanoic acid amide rennin inhibitor, but differs from the instantly claimed invention by failing to show the microemulsion to be one that converts to an oil in water microemulsion upon dilution with an aqueous medium.

Owen et al teach convertible microemulsion formulations in an analogous art for the purpose of teaching "improved drug delivery systems" (see col. 2, lines 53-54) and are biologically compatible in that they are non-toxic and contain biodegradable or non-absorbable materials, which provide for significantly increase bioavailablity of the delivered active agent (see col. 31, lines 7-9).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the microemulsion of Silver with the microemulsion of Owen et al because Owen et al teach the advantages of convertible microemulsions that provide for significantly increased bioavailablity of the delivered active agent at the desired location.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining convertible microemulsions for the delivery of aliskiren, or another renin inhibit derivative thereof at taught by Silver et al because Owen et al teach that the microemulstion formulations are biologically compatible in that they are non-toxic and contain biodegradable or non-absorbable materials that are readily available for formulation into drug delivery compositions.

Silver et al in view of Owen et al obviate the instantly claimed invention as now claimed.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goschke et al (US Pat. 5,646,143; 5705658 (see col. 14, 45-46 and all claims);US005654445A; 5627182; US005559111A) are cited to show delta amino gamma hydroxyl omega aryl aldanoic acid amide derivatives.

6. US 20050118254A1 is cited to s how microemulsion preconcentrates that comprise an active agent component.

7. US006217886B1 is cited to show renin inhibiting peptides [0063] for treatment of cardiovascular conditions, through formulation into Captex ® [0078; 0086;0090].

8. EP000760237A1 is cited to show oil in water microemulsions.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp March 21, 2007

MARK NAVARRO
PRIMARY EXAMINER